UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA
ex rel.
CONSTANCE A. CONRAD

Plaintiffs,

v.

WYETH BIOPHARMA,
f/k/a Genetics Institute, Inc.,
A.H. ROBINS CO.,
ABBOTT LABORATORIES, INC.,
AKZO NOBEL, INC.,
ALPHARMA USPD, INC.,
AMERICAN HOME PRODUCTS, through
Wyeth-Ayerst Laboratories
AMERICAN NATIONAL RED CROSS,
AMERISOURCE HEALTH SERVICES CORP.,
d/b/a AMERICAN HEALTH PACKAGING,
AMGEN, INC.,
AMIDE PHARMACEUTICAL, INC.,
ARMOUR PHARMACEUTICAL COMPANY
AXCAN PHARMA US, INC.,
BARRE-NATIONAL, INC.,
BAXTER HEALTHCARE CORP.,
BAYER CORP.,
BRECKENRIDGE, INC.,
CIMA LABS, INC.,
COLGATE ORAL PHARMACEUTICALS, INC.,
DRUG DISTRIBUTORS, INC.,
ECKERD DRUG CO.,
ECONOLAB, INC.
ETHEX CORP.,
EXCELLUM PHARMACEUTICALS, INC.,
GENETECH, INC.,
GENEVA PHARMACEUTICALS, INC.,
GOLDLINE LABORATORIES, INC.,
HOLLISTER STIER LABORATORIES, INC.,
IVAX PHARMACEUTICALS, INC.,
JEROME STEVENS PHARMACEUTICALS, INC.,
KNOLL PHARMACEUTICAL CO.,
MAJOR PHARMACEUTICALS, INC.,
MORTON GROVE PHARMACEUTICALS, INC.,
MURFREESBORO PHARMACY, INC.,
MUTUAL PHARMACEUTICAL CO., INC.,

SEALED

Civil Action No.

02 CV 11738 GAO

FILED UNDER SEAL 1/11/2011
PURSUANT TO JG
31 U.S.C. § 3730(b)(2)

RECEIPT # 41531
AMOUNT $ 150.00
SUMMONS ISSUED NO
LOCAL RULE 4.1 /
WAIVER FORM /
MCF ISSUED
BY DPTY. CLK. SES
DATE 8/29/02

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NATIONAL PHARMPAK SERVICES, INC.,
ORTHO-McNEIL PHARMACEUTICAL, INC.,
PADDOCK LABORATORIES, INC.,
PAN AMERICAN LABORATORIES, INC.,
PECOS PHARMACEUTICALS, INC.,
PHARMACEUTICAL ASSOC, INC.,
PHARMEDIX, INC.,
PUREPAC PHARMACEUTICAL CO.
QUALITEST PHARMACEUTICALS, INC.,
RANBAXY PHARMACEUTICALS, INC.,
RID, INC.,
ROXANE LABORATORIES, INC.,
SAVAGE LABORATORIES, INC.,
SCHERING-PLOUGH CORPORATION,
SCHWARZ PHARMA, INC.,
SIDMACK LABORATORIES, INC.,
SOLVAY PHARMACEUTICALS, INC.,
UNITED RESEARCH LABORATORIES, INC.,
VINTAGE PHARMACEUTICALS, INC
WAL MART STORES, INC.,
WARNER CHILCOTT, INC.,
d/b/a W. C. LABORATORIES,
WATSON LABORATORIES, INC.,
ZENITH LABORATORIES, INC.,
JOHN DOES MANUFACTURERS 58 - 107,
JANE DOES LABELERS 108 - 157,
JACK DOES DISTRIBUTORS 158 - 207
JIM DOES RETAILERS 208- 257

Defendants.

**FALSE CLAIMS ACT COMPLAINT**

**INTRODUCTION**

1. CONSTANCE A. CONRAD ("Relator") brings this action on behalf of the UNITED STATES OF AMERICA for treble damages and civil penalties arising from the DEFENDANTS' conduct in violation of the Federal Civil False Claims Act, 31 U.S.C. § 3729, et seq. ("FCA"). The violations arise out of requests for payment by Medicare, Medicaid, TriCare, and possibly other government agencies and programs (hereinafter, collectively the "Government Programs") based on false claims.

2. As required by the FCA, 31 U.S.C. § 3730(a) (2), the Relator has provided to the Attorney General of the United States and to the United States Attorney for the District of Massachusetts, simultaneous with the filing of this Complaint, a statement of all material evidence and information related to the Complaint. This disclosure statement is supported by material evidence known to Relator at the time of her filing, establishing the existence of the DEFENDANTS' legal responsibility for those false claims. Because the statement includes attorney-client communications and work product of Relator's attorneys, and is submitted to the Attorney General and to the United States Attorney in their capacity as potential co-counsel in the litigation, the Relator understands this disclosure to be confidential.

3. Relator is informed and believe that the pervasive conduct described herein began at least six (6) years before the filing of this Complaint, and has continued to date.

## FEDERAL JURISDICTION AND VENUE

4. The acts proscribed by 31 U.S.C. S 3729 et seq. and complained of herein occurred in part in the District of Massachusetts, and DEFENDANT does business in the District of Massachusetts. Therefore, this Court has jurisdiction over this case pursuant to 31 U.S.C. 3732 (a), as well as under 28 U.S.C. § 1345.

5. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a), because at least one of the DEFENDANTS reside in this District, at least one DEFENDANT transacts business in this District, and acts proscribed by section 31 U.S.C. § 3729 occurred in this District.

## PARTIES

6. The UNITED STATES funds the provision of medical care, including pharmaceutical products, for eligible citizens through Medicare, Medicaid, CHAMPUS, and other agencies and programs, acting through the Centers for Medicare & Medicaid Services ("CMS") within the U.S. Department of Health and Human services ("HHS"), and other agencies. (These programs will hereafter be referred to as "Government Programs," when referred to collectively.)

7. Relator, CONSTANCE A. CONRAD, is a resident of the state of Maryland. Ms. Conrad has 30 years experience in the federal healthcare programs field.

8. Relator brings this action based upon her independent and direct knowledge.

9. DEFENDANTS (described in paragraphs 39 through 67, and also the unknown DOE DEFENDANTS) manufacture, and/or promote, distribute and/or sell, for profit, over-the-counter and/or prescription pharmaceutical products, ultimately paid for by Government Programs, which have never been approved by the U.S. Food and Drug Administration ("FDA"), as required by law. DEFENDANTS' drugs will hereafter be referred to as "New Drug" or "New Drugs."

10. At all times relevant hereto, DEFENDANTS acted through their agents and employees and the acts of DEFENDANTS' agents and employees were within the scope of their agency and employment. The policies and practices alleged in this complaint were, on information and belief, set or ratified at the highest corporate levels of DEFENDANTS.

**Relevant History of the FDA Drug Approval Process**

11. The Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et. seq.*, as enacted in 1938, established a new system of drug regulation requiring pre-market approval before a drug could be marketed and sold in inter-state commerce.

12. The FDCA prohibits the sale of unapproved new drugs in interstate commerce: "No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application [to the FDA] is effective with respect to such drug."21 U.S.C. § 355(a). A drug manufacturer or distributor obtains FDA approval by submitting a new drug application (NDA) or abbreviated new drug application (ANDA) in accordance with the statute and FDA regulations. See 21 U.S.C. § 355(b)-(b)(1); 21 C.F.R. § 314.50 (detailing contents of NDA).

13. In 1962, the FDCA was amended to require NDAs to show that a drug is not only safe, but also effective for its intended uses. The 1962 amendments applied retroactively to drugs already on the market with approved NDAs based upon safety alone. In order to expedite review of the effectiveness of drugs with approved NDAs based solely upon their safety, the FDA instituted the Drug Efficacy Study Implementation (DESI) Program.

14. Under the DESI program, the FDA and the National Academy of Sciences-National Research Council (NAS-NRC) convened expert panels to consider the efficacy of classes of drugs already on the market with approved NDAs at the time of the 1962 amendments for supplemental NDA approval.

15. The DESI program was the basis for a short-lived policy under which the FDA permitted the continued sale of some drugs without approved NDAs. However, this policy was changed in 1975 because it was inconsistent with the FDCA, which requires pre-market approval before a drug is sold.

16. The FDCA, at 28 U.S.C. §321(p)(1), defines a "new drug" to be:

> Any drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labelling thereof . . . .

17. Where a drug contains a combination of drugs, the regulations at 21 C.F.R. 310.3(h)(2) and (3), state that the newness of a drug may arise by reason of the newness for a drug use of a combination of two or more substances, none of which is a new drug; or the newness for drug use of the proportion of a substance in combination, even though such combination containing such substance in other proportion is not a new drug.

18. Upon approval of the NDA, the FDA publishes a listing of the drug and all patents on the drug's approved aspects in a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluation," also known as the "Orange Book."

## The Medicaid Program

19. Medicaid is a federally assisted grant program for the states. Medicaid enables the states to provide medical assistance and related services to needy individuals. Centers for Medicaire and edicaid Services ("CMS"), formerly known as Health Care Financing Administration ("HCFA"), a component agency of HHS, administers Medicaid on the federal level. Within broad federal rules, however, each state decides who is eligible for Medicaid, the services covered, payment levels for services and administrative and operation procedures. The states directly reimburse providers for pharmaceutical products, with the state obtaining the federal share of the payment from accounts which draw on funds of the United States Treasury. The

Federal share of each state's Medicaid program varies state by state and is called Federal Financial Participation ("FFP").

20. Enrolled providers of medical services to Medicaid recipients are eligible for reimbursement for covered medical services under the provisions of Title XIX of the 1965 Amendments to the Federal Social Security Act (SSA). By becoming a participating provider in Medicaid, enrolled providers agree to abide by the rules, regulations, policies and procedures governing reimbursement, and to keep and allow access to records and information required by Medicaid. In order to receive Medicaid funds, enrolled providers, together with authorized agents, employees, and contractors, are required to abide by all the provisions of the SSA, the regulations promulgated by CMS under the SSA, and all applicable policies and procedures issued by both CMS and the applicable state Medicaid agency.

21. Federal law requires *at a minimum* that states may only reimburse and cover prescription drugs that are approved by the FDA. 42 U.S.C. §1396(a)(54) provides:

> in the case of a State plan that provides medical assistance for covered outpatient drugs (as defined in section 1396r-8(k) of this title), comply with the applicable requirements of section 1396r-8 of this title;

22. 42 U.S.C. §*1396r*-8(k)(2) provides that covered outpatient drugs are only: (1) FDA approved drugs; (2) Drugs which were sold prior to October 1962 and which have not been classified as a "New Drug." The statutory definition encompasses all *FDA approved* prescription drugs and biologicals, except for vaccines or drugs that fall within the limiting definition in 42 U.S.C. §1396r-8(k)(2), not applicable in the instant case.

23. Medicaid is, in most circumstances, available only for "covered outpatient drugs." As such, Federal law *mandates* that state expenditures for prescription drugs may only be made for claims for FDA-approved drugs. Federal regulations, such as 42 C.F.R. §441.25, follow this requirement.

24. Pharmaceutical *manufacturers* participating in Medicaid programs rebate to the states a portion of the price of drugs purchased for Medicaid purposes. See 42 U.S.C. §1396r-8(a)(1).

25. Pharmaceutical manufacturers that want their drugs available to Medicaid beneficiaries under the Medicaid program must enter into a Drug Rebate Agreement with the HHS Secretary to provide rebates. See 42 U.S.C. §1396r-8(a)(1), non-FDA approved drugs are not eligible to be included by the manufacturer as a "covered drug," as defined in the Drug Rebate Agreement, which each DEFENDANT has entered into.

26. The Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program (Form CMS-64) is the accounting statement which States, in accordance with 42 C.F.R. §430.30(c), must submit each quarter under title XIX of the Social Security Act (the Act). It shows the disposition of Medicaid grant funds for the quarter being reported and previous fiscal years, the recoupment made or refunds received, and income earned on grant funds.

27. The amounts reported on Form CMS-64 and its attachments must be actual expenditures for which all supporting documentation, in readily reviewable form, has been compiled and is available immediately at the time the claim is filed. Form CMS-64 includes a category for pharmaceutical expenditures.

## The Medicare Program

28. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare Program, to pay for the costs of certain healthcare services. Entitlement to Medicare is based on age, disability or affliction with certain diseases.

29. At all material times, FDA approval has generally been required for Medicare reimbursement for prescription drug coverage, albeit such Medicare coverage is extremely limited.

## The TRICARE/CHAMPUS Program

30. TRICARE Management Activity, formerly known as CHAMPUS, is a program of the Department of Defense that helps pay for covered civilian health care obtained by military beneficiaries, including retirees, their dependents, and dependents of active-duty personnel. 10 U.S.C. §§ 1079, 1086; 32 C.F.R. Part 199. TRICARE contracts with fiscal intermediaries and managed care contractors to review and pay claims, including claims submitted for prescription drugs.

31. At all material times, FDA approval of prescription drugs has been required for TRICARE reimbursement, or "cost-sharing." Pursuant to Chapter 7, Section 7.1 of the TRICARE Policy Manual, drugs may be cost-shared if and only if "[t]he drug is approved for marketing by the U.S. Food and Drug Administration."

**Substantive Allegations**

32. In sum, each Government Program excludes coverage for non-FDA approved drugs. This exclusion is consistent with the mandate of each program, that they will only pay for what is reasonable and necessary. Unsafe and/or ineffective drugs are neither reasonable nor necessary.

33. The New Drugs have never, to date, been approved by the FDA as safe and/or effective. To be sure, the New Drugs are not listed in the "Orange Book" (which identifies drug products approved on the basis of safety and effectiveness by the FDA under the Act.) Because of a true lack of resources, the FDA has never taken steps to enjoin the sale of the New Drugs identified herein. DEFENDANTS, however, have intentionally and knowingly taken advantage of the FDA's lack of resources, and resulting lack of enforcement.

34. DEFENDANTS (and their predecessors) have taken no steps to dispel the widely held public and medical belief that their respective New Drugs are FDA-approved; instead, they have fostered such belief.

35. DEFENDANTS concealed material facts from Government Programs, physicians and patients, in product packaging, labeling, medical advertising, direct consumer advertising, promotional campaigns and materials, among other ways, regarding the safety and effectiveness of their products.

36. DEFENDANTS falsely and knowingly omitted, suppressed or concealed the fact that their respective New Drugs were not FDA-approved.

37. DEFENDANTS engaged in calculated silence despite their knowledge of the growing Government Programs, physician and patient acceptance of their New

Drugs, and did so because the prospect of huge future profits outweighed health and safety issues, all to the significant detriment of Government Programs and patients.

38. Federal law requires that covered drugs of Government Programs (Medicaid, Medicare, TRICARE, VA, etc.) must be FDA-approved. Despite this:

a. DEFENDANTS have knowingly led Government Programs to believe that the New Drugs are FDA-approved drugs. Had each Government Program known that the New Drugs were not FDA-approved, the claims would not have been paid;

b. DEFENDANTS have knowingly led physicians and other medical professionals to believe that the New Drugs are safe and effective and FDA-approved, despite the fact that they have not been FDA-approved, and despite knowing, that safer and/or more effective alternative methods of relief were available;

c. States, relying on their Medicaid program personnel, have paid for the New Drugs. Moreover, states have certified to the United States, in periodic, required reports, that their Medicaid programs only paid for FDA-approved drugs. Any state that paid for any of the New Drugs and filed claims for FFP for those payments did so in violation of the federal coverage requirements and the law regarding the FFP, presumably unknowingly;

d. TRICARE, relying on its contractors and agents, has unknowingly paid for some of the New Drugs in violation of the coverage requirements of TRICARE Policy Manual, Chapter 7.1; and

e. Medicare, relying on its contractors and agents, has unknowingly paid for some of the New Drugs in violation of federal law.

**Identification of New Drugs**

39. The following DEFENDANTS are responsible for introducing **Phenobarbital (generic name)**, into interstate commerce, by manufacturing, developing, promoting, labeling, distributing, and/or selling said drug. Said DEFENDANTS caused and/or submitted false claims to Government Programs:

i. ALPHARMA USPD, INC., located at 200 Elmora Ave., Elizabeth, NJ 07207.

ii. PUREPAC PHARMACEUTICAL CO., located at attn: Charlene Salmorin, 200 Elmora Ave., Princeton, NJ 07207.

iii. QUALITEST PHARMACEUTICALS, INC., located at 1236 Jordan Rd., Huntsville, AL 35811.

iv. VINTAGE PHARMACEUTICALS, INC., located at 140 Vintage Dr., Huntsville, AL 35811.

v. BARRE-NATIONAL, INC., located at 333 Cassell Dr., Suite 3500, Baltimore, MD.

40. The following DEFENDANTS are responsible for introducing **Pancrelipase (generic name)**, under the brands set forth below, into interstate commerce, by manufacturing, developing, promoting, labeling, distributing, and/or selling said drug. Said DEFENDANTS caused and/or submitted false claims to Government Programs:

a. GOLDLINE LABORATORIES INC., located at 4400 Biscayne Blvd.,Miami, FL 33137.

b. UNITED RESEARCH LABORATORIES, INC., located at 1100 Orthodox St., Philadelphia, PA 19124.

c. MUTUAL PHARMACEUTICAL CO., INC., located at 1100 Orthodox St., Philadelphia, PA 19124.

d. PECOS PHARMACEUTICALS, INC., located at 3510 N. Lake Creek Dr., Jackson, WY 83001.

e. MAJOR PHARMACEUTICALS, INC., located at 31778 Enterprise Dr., Livona, MI 48150.

f. SOLVAY PHARMACEUTICALS, INC., located at 901 Sawyer Rd., Marietta, GA 30062 (under the brand name **"Creon®"**).

g. ORTHO-McNEIL PHARMACEUTICAL, INC., located at 1000 Rte. 202, Raritan, NJ 08869 (under the brand name **"Pancrease®"**).

h. BRECKENRIDGE, INC., located at 1141 S. Rogers Cir., Suite 3, Boca Raton, FL 33487 (under the brand name **"Panokase®"**).

i. ECONOLAB, INC., located at PO Box 85543,Westland, MI 48185 (under the brand name **"Panokase®"**).

j. MAJOR PHARMACEUTICALS, INC., located at 31778 Enterprise Dr., Livona, MI 48150.(under the brand name **"Panokase®").**

k. AXCAN PHARMA US, INC., located at 22 Inverness Center Pkwy., Birmingham, AL 35242 (under the brand name **"Ultrase®"**).

l. PADDOCK LABS, located at 3940 Quebec Ave., Minneapolis, MN 55427 (under the brand name **"Viokase®"**).

41. The following DEFENDANTS are responsible for introducing **Docusate Sodium (generic name)**, which brand and generic names include **"Docusate Sodium Syrup," "Docusate Sodium Liquid," and "Docusate Sodium Capsules"** into interstate commerce, by manufacturing, developing, promoting, labeling, distributing, and/or selling said drug. Said DEFENDANTS caused and/or submitted false claims to Government Programs:

a. GOLDLINE LABORATORIES INC., located at 4400 Biscayne Blvd.,Miami, FL 33137.

b. UNITED RESEARCH LABORATORIES, INC., located at 1100 Orthodox St., Philadelphia, PA 19124.

c. GENEVA PHARMACEUTICALS, INC., located at 2555 W. Midway Ave., Broomfield, CO 80038-0446.

42. The following DEFENDANTS are responsible for introducing the brand name drug **Cipro I.V.® (generic name is "Fluoroquinolone")**, into interstate commerce, by manufacturing, developing, promoting, labeling, distributing, and/or selling said drug. Said DEFENDANTS caused and/or submitted false claims to Government Programs:

a. BAYER CORP., located at 400 Morgan Lane, West Haven, CT 06516 (also sold under the generic name **"Ciprofloxacin")**.

b. ABBOTT LABORATORIES, INC., located at 100 Abbott Park Rd., D387, AP 6C1, Abbott Park, IL 60064.

c. HOLLISTER STIER LABORATORIES, INC., located at PO Box 3145, Spokane, WA.

d. NATIONAL PHARMPAK SERVICES, INC., located at 3540 East Pike, Zanesville, OH 43701.

43. The following DEFENDANTS are responsible for introducing the brand name drug **Mandelamine® (generic name is also "Methenamine")**, into interstate commerce, and in doing so, caused and/or submitted false claims to Government Programs:

a. MURFREESBORO PHARMACY, INC., located at 1843 Memorial Blvd., Murfreesboro, TN 37129.

b. WARNER CHILCOTT, INC., D/B/A W. C. LABORATORIES, located at 100 Enterprise Dr., Ste 280, Rockaway, NJ 07866.

44. The following DEFENDANTS are responsible for introducing the brand name drug **Levsin® (generic name is "Hyoscyamine Sulfate")**, into interstate commerce, by manufacturing, developing, promoting, labeling, distributing, and/or selling said drug. Said DEFENDANTS caused and/or submitted false claims to Government Programs:

a. SCHWARZ PHARMA, INC., located at 6140 W. Executive DrMequon, WI 53092.

b. AMERISOURCE HEALTH SERVICES CORP., D/B/A AMERICAN HEALTH PACKAGING, located at 2550 John Glenn Ave., Ste. A, Columbus, OH 43217.

c. DRUG DISTRIBUTORS, INC., located at 1111 South Adams St., Bluffton, IN 46714.

d. ECKERD DRUG CO., located at PO Box 4689, Clearwater, FL 33758.

e. WAL MART STORES, INC., located at 1201 Moberly Lane, Bentonville, AR 72716.

45. The following DEFENDANTS are responsible for introducing the brand name drug **Chromagen®**, into interstate commerce, by manufacturing, developing, promoting, labeling, distributing, and/or selling said drug. Said DEFENDANTS caused and/or submitted false claims to Government Programs:

a. SAVAGE LABORATORIES, INC., 60 Baylis Rd., Melville, NY 11747 (under the brand names **"Chromagen FA Capsules®" and "Chromagen Forte Solfgel®").**

46. The following DEFENDANTS are responsible for introducing **Hyoscyamine Sulfate (generic name)**, in 15 different drugs, into interstate commerce, by manufacturing, developing, promoting, labeling, distributing, and/or selling said drug. Said DEFENDANTS caused and/or submitted false claims to Government Programs:

a. SCHWARZ PHARMA, INC., located at 6140 W. Executive DrMequon, WI 53092.

b. AMIDE PHARMACEUTICAL, INC., located at 101 East Main St., Little Falls, NJ 07424.

c. ETHEX CORP., located at 10888 Metro Ct., Saint Louis, MO 63043.

d. EXCELLUM PHARMACEUTICALS, INC., located at 3G Oak Rd., Fairfield, NJ 07004.

47. The following DEFENDANTS are responsible for introducing **Quinine Sulfate (generic name)**, into interstate commerce, by manufacturing, developing, promoting, labeling, distributing, and/or selling said drug. Said DEFENDANTS caused and/or submitted false claims to Government Programs:

a. IVAX PHARMACEUTICALS, INC., located at 4400 Biscayne Blvd., Miami, Fl 33137.

b. MUTUAL PHARMACEUTICAL CO., INC., located at 1100 Orthodox St., Philadelphia, PA 19124.

c. RID, INC., located at 609 North Mednik Ave., Los Angeles, CA 90022.

d. UNITED RESEARCH LABORATORIES, INC., located at 1100 Orthodox St., Philadelphia, PA 19124.

e. WATSON LABORATORIES, INC., located at Mount Ebo Rd South, Brewster, NY 10509.

f. ZENITH LABORATORIES, INC., located at 140 LeGrand Ave., Northvale, NJ.

48. The following DEFENDANTS are responsible for introducing the brand name drug **Niferex® (generic name is "Elemental Iron")**, into interstate commerce, by manufacturing, developing, promoting, labeling, distributing, and/or selling said drug. Said DEFENDANTS caused and/or submitted false claims to Government Programs:

a. SCHWARZ PHARMA, INC., located at 6140 W. Executive Dr., Mequon, WI 53092.

b. A.H. ROBINS CO., Division of American Home Products Corp., located at 5 Giralda Farms, Madison, NJ.

49. The following DEFENDANT is responsible for introducing the brand name drug **Monarch-M®,(generic name is "Factor VIII")**, into interstate commerce, by manufacturing, developing, promoting, labeling, distributing, and/or selling said drug. Said DEFENDANTS caused and/or submitted false claims to Government Programs:

a. AMERICAN NATIONAL RED CROSS, located at 1730 East St. Northwest, Washington, DC 20006.

50. The following DEFENDANT is responsible for introducing the brand name drug **Panlor®,** into interstate commerce, by manufacturing, developing, promoting, labeling, distributing, and/or selling said drug. Said DEFENDANTS caused and/or submitted false claims to Government Programs:

a. PAN AMERICAN LABORATORIES, INC., located at PO Box: 8950, MANDEVILLE, LA 70470.

51. The following DEFENDANTS are responsible for introducing the brand name drug **Codeine Sulfate®, (generic name is "Codeine Sulfate")** into interstate commerce, by manufacturing, developing, promoting, labeling, distributing, and/or selling said drug. Said DEFENDANTS caused and/or submitted false claims to Government Programs:

a. KNOLL PHARMACEUTICAL CO., located at 3000 Continental Dr North, Mount Olive, NJ 07828.

b. ROXANE LABORATORIES, INC., located at PO Box 6532, Columbus, OH 43216.

52. The following DEFENDANTS are responsible for introducing **Bisacodyl (generic name)** into interstate commerce, by manufacturing, developing, promoting, labeling, distributing, and/or selling said drug. Said DEFENDANTS caused and/or submitted false claims to Government Programs:

a. SCHERING-PLOUGH CORPORATION, located at 2000 Galloping Hill Rd., Kenilworth, NJ 07033 (under the brand name "Correctol®").

53. The following DEFENDANT is responsible for introducing the brand name drug **Necon® (generic names are "Norethindrone" and "Ethinyl Estradial.")**, into interstate commerce, by manufacturing, developing, promoting, labeling, distributing, and/or selling said drug. Said DEFENDANTS caused and/or submitted false claims to Government Programs:

a. WATSON LABORATORIES, INC., located at Mount EBO South, Brewster, NY 10509.

54. The following DEFENDANTS are responsible for introducing **Levothyroxine Sodium (generic name)** into interstate commerce, by manufacturing, developing, promoting, labeling, distributing, and/or selling said drug. Said DEFENDANTS caused and/or submitted false claims to Government Programs:

a. QUALITEST PHARMACEUTICALS, INC., located at 1236 Jordan Rd., Huntsville, AL 35811.

b. UNITED RESEARCH LABORATORIES, INC., located at 1100 Orthodox St., Philadelphia, PA 19124.

c. VINTAGE PHARMACEUTICALS, INC., located at 140 Vintage Dr., Huntsville, AL 35811.

d. JEROME STEVENS PHARMACEUTICALS, INC., located at 60 Da Vinci Dr., Bohemia, NY.

e. AMERICAN HOME PRODUCTS, through WYETH-AYERST LABORATORIES, located at 555 E. Lancaster Ave., St. Davids, PA 19087.

55. The following Defendant is responsible for introducing the brand name drug **Feiba VH® (generic name is "Antihemophilic factor")** into interstate commerce, by manufacturing, developing, promoting, labeling, distributing, and/or selling said drug. Said DEFENDANTS caused and/or submitted false claims to Government Programs:

a. BAXTER HEALTHCARE CORP., located at Hyland Immuno, Glendale, CA 91203.

56. The following DEFENDANTS are responsible for introducing the brand name drug Helixate® **(generic name is "Antihemophilic factor")** into interstate commerce, by manufacturing, developing, promoting, labeling, distributing, and/or selling said drug. Said DEFENDANTS caused and/or submitted false claims to Government Programs:

a. BAYER CORP., located at 400 Morgan Lane, West Haven, CT.

b. ARMOUR PHARMACEUTICAL COMPANY, located at 500 Arcola Rd., Collegeville, PA.

57. The following DEFENDANT is responsible for introducing the brand name drug **Solganal®** into interstate commerce, by manufacturing, developing, promoting, labeling, distributing, and/or selling said drug. Said DEFENDANTS caused and/or submitted false claims to Government Programs:

a. SCHERING-PLOUGH CORPORATION, located at 2000 Galloping Hill Rd., Kenilworth, NJ 07033.

58. The following DEFENDANT is responsible for introducing the brand name drug **Nulev®(generic name "Hyoscyamine Sulfate)** into interstate commerce, by manufacturing, developing, promoting, labeling, distributing, and/or selling said drug. Said DEFENDANTS caused and/or submitted false claims to Government Programs:

a. CIMA LABS, INC., located at 10000 Valley View Rd., Eden Prairie, MN 55344.

59. The following DEFENDANT is responsible for introducing the brand name drug **Refacto®(generic name "Antihemophilic factor")** into interstate commerce, by manufacturing, developing, promoting, labeling, distributing, and/or selling said drug. Said DEFENDANTS caused and/or submitted false claims to Government Programs:

a. WYETH BIOPHARMA (f/k/a Genetics Institute, Inc.), located at One Burtt Rd., Andover, MA.

60. The following DEFENDANT is responsible for introducing the brand name drug **Infergen® (generic name is "Interferon")** into interstate commerce, by

manufacturing, developing, promoting, labeling, distributing, and/or selling said drug. Said DEFENDANTS caused and/or submitted false claims to Government Programs:

a. AMGEN, INC., located at One Amgen Center Dr., Thousand Oaks, CA 91320.

61. The following DEFENDANT is responsible for introducing the brand name drug **Rituxan®(generic name is "Rituximab")** into interstate commerce, by manufacturing, developing, promoting, labeling, distributing, and/or selling said drug. Said DEFENDANTS caused and/or submitted false claims to Government Programs:

a. GENETECH, INC., located at 1 DNA Way, South San Francisco, CA 94080.

62. The following DEFENDANT is responsible for introducing the brand name drug **Prevident®(generic name is "Toothpaste")** into interstate commerce, by manufacturing, developing, promoting, labeling, distributing, and/or selling said drug. Said DEFENDANTS caused and/or submitted false claims to Government Programs:

a. COLGATE ORAL PHARMACEUTICALS, INC., located at 14335 Gillis Rd., Dallas, TX 75244.

63. The following DEFENDANT is responsible for introducing the brand name drug **Neumega®** into interstate commerce, by manufacturing, developing, promoting, labeling, distributing, and/or selling said drug. Said DEFENDANT caused and/or submitted false claims to Government Programs:

a. WYETH BIOPHARMA (f/k/a Genetics Institute, Inc.), located at One Burtt Rd., Andover, MA.

64. The following DEFENDANTS are responsible for introducing **Chloral Hydrate(generic name)**into interstate commerce, by manufacturing, developing,

promoting, labeling, distributing, and/or selling said drug. Said DEFENDANTS caused and/or submitted false claims to Government Programs:

a. MORTON GROVE PHARMACEUTICALS, INC., located at 6451 W. Main St., Morton Grove, IL 60053.

b. PHARMACEUTICAL ASSOC, INC., located at Div. Beach Products, 201 Delaware St., Greenville, SC 29605.

65. The following DEFENDANT is responsible for introducing **Triple Sulfa Vaginal Cream(generic name)**into interstate commerce, by manufacturing, developing, promoting, labeling, distributing, and/or selling said drug. Said DEFENDANTS caused and/or submitted false claims to Government Programs:

a. PHARMEDIX, INC. located at 3513 Breakwater Ave., Hayward, CA 94545.

66. The following DEFENDANTS are responsible for introducing **Salsalate (generic name salicylsalicylic)** into interstate commerce, by manufacturing, developing, promoting, labeling, distributing, and/or selling said drug. Said DEFENDANTS caused and/or submitted false claims to Government Programs:

a. QUALITEST PHARMACEUTICALS, INC., located at 1236 Jordan Rd., Huntsville, AL 35811.

b. SIDMACK LABORATORIES, INC., located at 17 West St., East Hanover, NJ 07936.

c. RANBAXY PHARMACEUTICALS, INC., located at Attn: Shirley Ternyik, 600 College Rd. East, Princeton, NJ 08540.

67. The following DEFENDANT is responsible for introducing **Zymase(generic name)**into interstate commerce, by manufacturing, developing, promoting, labeling, distributing, and/or selling said drug. Said DEFENDANT caused and/or submitted false claims to Government Programs:

a. AKZO NOBEL, INC., located at 300 South Riverside Plaza, Suite 2200, Chicago, IL 60606.

## COUNT I- FALSE CLAIMS ACT

68. Relator realleges and incorporates by reference paragraphs 1 - 67 as though fully set forth herein.

69. This is a claim by Relator, on behalf of The UNITED STATES OF AMERICA, for treble damages and penalties under the FCA, 31 U.S.C. §3729-3733 against DEFENDANTS for knowingly presenting, or causing to be presented false claims to Government Programs. For at least the preceding 6 years, through present, in the District of Massachusetts and elsewhere throughout the United States, DEFENDANTS have knowingly and willfully caused to be presented false claims.

70. Pursuant to 31 U.S.C. §3729(a)(1), DEFENDANTS have knowingly and directly submitted to the United States, through HHS, in their Medicaid Rebate Agreement, and subsequently in reports submitted to HHS each quarter for the 6 preceding years, false information in the form of listing non-covered drugs (under the Medicaid program), as "covered outpatient drugs," as that term is defined in the Medicaid Rebate Agreement. Based on the inclusion of the DEFENDANTS' New Drugs as "covered outpatient drugs," the United States Government and state governments relied on this information, and paid claims for said New Drugs.

71. By virtue of the false claims presented or caused to be presented by DEFENDANTS, the UNITED STATES OF AMERICA is entitled to three times the amount by which it was damaged, to be determined at trial, plus a civil penalty of not less than $5,000.00 and not more than $11,000.00 for each false claim presented or caused to be presented.

## COUNT II -THE FALSE CLAIMS ACT

72. Relator realleges and incorporates by reference paragraphs 1- 67 as though fully set forth herein.

73. This is a claim by Relator, on behalf of the UNITED STATES OF AMERICA, for treble damages and penalties under 31 U.S.C. §3729-3733 against DEFENDANTS for knowingly presenting or causing to be presented false claims to Government Programs. For at least the preceding 6 years, through present, in the District of Massachusetts, and elsewhere throughout the UNITED STATES, DEFENDANTS have knowingly and willfully caused to be presented false claims.

74. Pursuant to 31 U.S.C. §3729(a)(1) and 31 U.S.C. §3729(a)(2), DEFENDANTS have: (1) knowingly caused states to falsely certify (in quarterly reports) to the United States Government in various CMS Forms, including Form CMS-64, that all drugs paid for were in compliance with federal law, and other false certifications; and (2) knowingly caused pharmacies and other healthcare providers to submit HCFA-1500 claims for payment for prescription and non-prescription New Drugs, knowing that such claims would be submitted to the United States Government and state governments, and also knowing that such healthcare providers were unaware that they were submitting false claims.

75. By virtue of the false claims presented or caused to be presented by DEFENDANTS, the UNITED STATES OF AMERICA is entitled to three times the amount by which it was damaged, to be determined at trial, plus a civil penalty of $10,000.00 for each false claim presented or caused to be presented.

WHEREFORE, Relator respectfully request this Court to enter Judgment against DEFENDANTS, as follows:

(a) That the U.S. be awarded damages in the amount of three times the damages sustained by the U.S. because of the false claims alleged within this Complaint, as the Federal Civil False Claims Act, 31 U.S.C. § 3729 et seq. provides.

(b) That civil penalties of $11,000 be imposed for each and every false claim that DEFENDANT caused to be presented to the Government Programs under the Federal False Claims Act.

(c) That pre- and post-judgment interest be awarded, along with reasonable attorney's fees, costs, and expenses which the Relator necessarily incurred in bringing and pressing this case;

(d) That the Relator be awarded the maximum amount allowed pursuant the Federal False Claims Act.

(e) That this Court award such other and further relief as it deems proper.

Respectfully submitted,

John Roddy, BBO #424240
Frederic D. Grant, Jr., BBO #543115
Grant & Roddy
44 School Street, Suite 400
Boston, MA 02108
Telephone: (617) 248-8700
Telefax: (617) 248-0720

*Of Counsel*:
Kenneth J. Nolan, P.A.
350 E. Las Olas Blvd., Suite 1270
Fort Lauderdale, FL 33301
Phone: (954) 779-3943
Fax: (954) 779-3937

Dated: August 29, 2002